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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/088,951	06/02/98	CHEEVER M	920010.535

EXAMINER	
CANELLA,K	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/088,951	Applicant(s) Cheever et al
	Examiner Karen Canella	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 7-9, 11, and 12* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 7-9, 11, and 12* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. The request filed on 7/16/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/088,951 is acceptable and a CPA has been established. An action on the CPA follows.

2. Please note that the examiner assigned to your application has changed.

3. Claims 1, 11 and 12 have been amended. Claims 1, 7-9, 11 and 12 are pending and examined on the merits.

Priority

4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. as follows: In order for the instant application to draw priority from the 08/625,101 application, the method of the instant application must be disclosed in the 08/625,101 application to sufficiently comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971). As there is no mention of a method for overcoming tolerance to tumor antigens or eliciting an immune response to a human self tumor antigen by the administration of homologous tumor antigens from non-human source in parent application 08/625,101, now US 5,869,445, the priority date of the instant application will be based on the provisional application 60/048,406, filed 6/3/97.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 7-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatta et al (Proceed Am Assoc Cancer Res, March 1997, Vol. 38, p. 403) in view of what is suggested in the reference. Claim 1 is drawn to a method of eliciting or enhancing an immune response to a human self tumor antigen comprising immunizing a human being with a composition comprising a protein or a portion thereof with an amino acid sequence native to a non-human source wherein the non-human protein or portion thereof has at least 80% homology to said human antigen but is not identical to the antigen. Claim 7 embodies the restriction that the antigen is organ specific or a tissue-specific differentiation antigen. Claim 8 further restricts claim 7 in that the antigen is associated with prostate cancer and claim 9 further restricts claim 8 to the PAP antigen. Claim 11 embodies a composition comprising a pharmaceutically acceptable carrier or diluent. Chatta et al teach a method of inducing immunity to prostatic acid phosphatase (PAP) in rats by immunizing with human PAP. Chatta et al do not teach a method of inducing an immune response to PAP in humans by immunizing with rat PAP. However, as the title of the publication indicates, the teachings of Chatta can be translated to immunotherapy of human prostate cancer. It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to elicit or enhance an immune response to the human self tumor antigen, PAP, by immunizing a human with rat PAP.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Chatta et al on the efficacy of using a molecular mimic to break tolerance to endogenous PAP in a organism wherein PAP is associated with tumor burden.

8. Claims 1, 7, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Disis et al (Journal of Immunology, 1996 May, Vol. 156, pp. 3151-3158) in view of any of Dyrberg and Oldstone, in: Current topic in Microbiology and Immunology, 1989, Vol. 130, pp. 25-37), or Naftzger et al (PNAS, Dec 1996, Vol. 93, pp. 14809-14814) or Mamula et al (Arthritis and Rheumatism, 1992, Vol. 35, suppl., p. S38) or Fedoseyeva et al (Transplantation, 1996, Vol. 61, pp. 679-683) or Mahi-Brown (Journal of Reproductive Immunology, 1992, Vol. 21, pp. 29-46). The embodiments of claims 1, 7 and 11 are summarized above. Claim 12 embodies the use of an adjuvant with the composition of the non-human protein. Disis et al teaches a method for inducing or enhancing immunity to the Her-2/neu antigen in rats by immunizing with peptides corresponding to sub-dominant epitopes of rat Her-2/neu. Disis et al further teaches that immunization with intact rat Her-2/neu failed to elicit rat neu specific responses. Disis et al do not teach immunization of rats with intact human Her-2/neu or immunization of humans with intact rat neu as methods for overcome tolerance to Her-2/neu. Dyberg and Oldstone teach the concept of "molecular mimicry" wherein autoimmunity to a host self protein can be induced by homologous but non-identical epitopes produced by viral infections. Naftzger et al teach that tolerance to mouse melanocyte dedifferentation antigen can be broken by immunizing mice with altered melanocyte differentiation antigen in the form of a homologous xenogeneic protein or protein expressed in insect cells. Mamula et al teach a method to induce an immune response to self cytochrome C in mice by immunizing with human cytochrome C or the immunodominant epitope of human cytochrome C consisting of residues 81-104. Fedoseyeva et al teach that transplantation of BALB/c mice (H2d) with spenocytes from allogenic BALB/c mice (H2a) resulted in the recognition of the immunodominant self peptide Dd as tolerance to said self

peptide was broken by the presentation of the crossreactive peptide Kk. Ruoslahti et al teach that mice immunized with zona pellucida antigens from rat or pig developed an immune response against self zona pellucida as evidenced by disrupted follicular development. It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to immunize humans with intact rat neu protein. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Disis et al on the Her-2 antigen as an appropriate tumor target in humans and the need for a method to overcome self tolerance to Her-2; and the further teachings of Dyberg and Oldstone, Naftzger et al, Mamula et al, Fedoseyeva et al or Ruoslahti et al on the concept of inducing immunity to self antigens in a host by presenting to said host a homologous but non-identical protein. None of the references specifically teach an 80% amino acid identity to the self protein, but said level of identity would be inherent in the homologous proteins taught by the prior art.

9. Claims 1, 7-9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spitler et al (US 5,925,362) in view of any of Dyrberg and Oldstone, in: Current topic in Microbiology and Immunology, 1989, Vol. 130, pp. 25-37), or Naftzger et al (PNAS, Dec 1996, Vol. 93, pp. 14809-14814) or Mamula et al (Arthritis and Rheumatism, 1992, Vol. 35, suppl., p. S38) or Fedoseyeva et al (Transplantation, 1996, Vol. 61, pp. 679-683) or Mahi-Brown (Journal of Reproductive Immunology, 1992, Vol. 21, pp. 29-46). The embodiments of the instant claims are summarized in paragraphs 7 and 8 supra. Spitler et al teach a method to elicit an immune response in humans by vaccination with human tumor antigens such as PSA, PAP, PMSA and adjuvant. Spitler et al teach that human PSA expressed recombinantly in insect cells result in post-translationally modified PSA which has different immunogenicity from PSA recombinantly expressed in human cells (column 5, lines 54-59). Spitler et al do not teach a method to elicit or enhance an immune response to by immunization with a xenogeneic protein homologous to PSA or PAP. However, for the specific reasons stated above, any of Dyberg and Oldstone, Naftzger et

al, Mamula et al, Fedoseyeva et al or Ruoslahti et al teach the concept of inducing immunity to self antigens in a host by presenting to said host a homologous but non-identical protein. It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to elicit or enhance an immune response to human PSA or PAP by immunization with a xenogeneic protein homologous to PSA or PAP. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Dyberg and Oldstone, Naftzger et al, Mamula et al, Fedoseyeva et al or Ruoslahti et al on the concept of inducing immunity to self antigens in a host by presenting to said host a homologous but non-identical protein. None of the references specifically teach an 80% amino acid identity to the self protein, but said level of identity would be inherent in the homologous proteins taught by the prior art.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ANTHONY C. CAPUTA
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Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
September 7, 2001